

Clinical Trials at Gabrail Cancer Center Have Contributed to the Approval of the Following Oncology Drugs

2023

- Tucatinib (Tukysa, Seagen Inc.) in combination with trastuzumab for RAS wild-type HER2-positive unresectable or metastatic colorectal cancer that has progressed; January 2023
- Zanubrutinib (Brukinsa, BeiGene USA, Inc.) for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL); January 2023
- Pembrolizumab (Keytruda, Merck) for adjuvant treatment following resection and platinum-based chemotherapy for stage IB (T2a $\geq$ 4 cm), II, or IIIA non-small cell lung cancer (NSCLC); January 2023
- Elacestrant (Orserdu, Stemline Therapeutics, Inc.) for postmenopausal women or adult men with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression; January 2023
- Pembrolizumab (Keytruda, Merck) with platinum-containing chemotherapy as neoadjuvant treatment, and with continuation of single-agent pembrolizumab as post-surgical adjuvant treatment for resectable (tumors $\geq$ 4 cm or node positive) non-small cell lung cancer (NSCLC); October 2023
- Toripalimab-tpzi (LOQTORZ, Coherus BioSciences, Inc.) with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent, locally advanced nasopharyngeal carcinoma (NPC); October 2023
- Pembrolizumab (Keytruda, Merck) to be used with gemcitabine and cisplatin for locally advanced unresectable or metastatic biliary tract cancer (BTC); October 2023
- Pembrolizumab (Keytruda, Merck) with trastuzumab, fluoropyrimidine, and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma; November 2023
- Enzalutamide (Xtandi, Astellas Pharma US, Inc.) for non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR); November 2023

2022

- Pembrolizumab (Keytruda, Merck), as a single agent, for patients with advanced endometrial carcinoma; March 2022
- Fam-trastuzumab deruxtecan-nxki (Enhertu, Daiichi Sankyo, Inc.) for adult patients with unresectable or metastatic HER2-positive breast cancer; May 2022
- Darolutamide (Nubeqa, Bayer HealthCare Pharmaceuticals Inc.) tablets in combination with docetaxel for adult patients with metastatic hormone-sensitive prostate cancer (mHSPC); August 2022
- Fam-trastuzumab deruxtecan-nxki (Enhertu, Daiichi Sankyo, Inc.) for adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC); August 2022
- Durvalumab (Imfinzi, AstraZeneca UK Limited) in combination with gemcitabine and cisplatin for adult patients with locally advanced or metastatic biliary tract cancer (BTC); September 2022
- Futibatinib (Lytgobi, Taiho Oncology, Inc.) for adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements; September 2022
- Cemiplimab-rwlc (Libtayo, Regeneron Pharmaceuticals, Inc.) in combination with platinum-based chemotherapy for adult patients with advanced non-small cell lung cancer (NSCLC) with no EGFR, ALK, or ROS1 aberrations; November 2022

2021

- Fam-trastuzumab deruxtecan-nxki (Enhertu, Daiichi Sankyo) for adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal (GEJ) adenocarcinoma; January 2021
- Cemiplimab-rwlc (Libtayo, Regeneron Pharmaceuticals, Inc.) for patients with locally advanced basal cell carcinoma (laBCC); February 2021
- Melphalan flufenamide (Pepaxto, Oncopeptides AB) in combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma; February 2021
- Isatuximab-irfc (Sarclisa, sanofi-aventis U.S. LLC) in combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma; March 2021
- Daratumumab and hyaluronidase-fihj (Darzalex Faspro, Janssen Biotech, Inc.) in combination with pomalidomide and dexamethasone for adult patients with multiple myeloma; July 2021
- Lenvatinib (Lenvima, Eisai) plus pembrolizumab (Keytruda, Merck) for first-line treatment of adult patients with advanced renal cell carcinoma; August 2021
- Ruxolitinib (Jakafi, Incyte Corp.) for chronic graft-versus-host disease (cGVHD); September 2021
- Asciminib (Scemblix, Novartis AG) for patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs); October 2021
- Daratumumab + Hyaluronidase-fihj (Darzalex Faspro, Janssen Biotech, Inc.) and Carfilzomib (Kyprolis, Amgen, Inc.) plus dexamethasone for adult patients with relapsed or refractory multiple myeloma; November 2021

2020

- Pembrolizumab (KEYTRUDA, Merck & Co. Inc.) for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy; January 2020
- Durvalumab (IMFINZI, AstraZeneca) in combination with etoposide and either carboplatin or cisplatin as first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC); March 2020
- Pembrolizumab (KEYTRUDA, Merck) new dosing regimen for patients with advanced or metastatic melanoma; April 2020
- Daratumumab and hyaluronidase-fihj (DARZALEX FASPRO, Janssen Biotech, Inc.) for adult patients with newly diagnosed or relapsed/refractory multiple myeloma; May 2020
- Pomalidomide (POMALYST, Celgene Corporation) for adult patients with AIDS-related Kaposi sarcoma; May 2020
- Nivolumab (OPDIVO, Bristol-Myers Squibb Co.) plus Ipilimumab (YERVOY, Bristol-Myers Squibb Co.) as first-line treatment for patients with metastatic non-small cell lung cancer whose tumors express PD-L1 ($\geq 1\%$) with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; May 2020
- Lurbinectedin (ZEPZELCA, Pharma Mar S.A.) for adult patients with metastatic small cell lung cancer; June 2020
- Pembrolizumab (KEYTRUDA, Merck & Co., Inc.) for the treatment of adult and pediatric patients with unresectable or metastatic solid tumors; June 2020
- Tazemetostat (TAZVERIK, Epizyme, Inc.), an EZH2 inhibitor, for adult patients with relapsed or refractory (R/R) follicular lymphoma (FL); June 2020
- Decitabine and Cedazuridine (INQOVI, Astex Pharmaceuticals, Inc.) for adult patients with myelodysplastic syndromes (MDS); July 2020
- Tafasitamab-cxix (MONJUVI, MorphoSys US Inc.), a CD19-directed cytolytic antibody, indicated in combination with lenalidomide for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma; July 2020
- Venetoclax (VENCLEXTA®, AbbVie Inc. and Genentech Inc.) for newly-diagnosed acute myeloid leukemia (AML); October 2020
- Osimertinib (TAGRISSO, AstraZeneca Pharmaceuticals LP) for adjuvant therapy after tumor resection in patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations; December 2020

2019

- Niraparib (ZEJULA) Tesaro, Inc., for patients with advanced ovarian, fallopian tube, or primary peritoneal cancer treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD)-positive status.
- Daratumumab (DARZALEX) Janssen, for adult patients with multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant (ASCT).
- Apalutamide (ERLEADA) Janssen Biotech, Inc, for patients with metastatic castration-sensitive prostate cancer (mCSPC).
- Pembrolizumab (KEYTRUDA) Merck, plus lenvatinib (LENVIMA) Eisai, for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.
- Fedratinib (INREBIC) Impact Biomedicines, Inc., for adults with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).
- Entrectinib (ROZLYTREK) Genentech Inc., for solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory standard therapy.
- Pexidartinib (TURALIO™) Daiichi Sankyo, for tenosynovial giant cell tumor.
- Pembrolizumab (KEYTRUDA) Merck, for advanced esophageal squamous cell cancer.
- Darolutamide (NUBEQA) Bayer HealthCare Pharmaceuticals Inc., for non-metastatic castration-resistant prostate cancer.
- Selinexor (XPOVIO) Karyopharm Therapeutics, in combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.
- Daratumumab (DARZALEX) Janssen Biotech, Inc., in combination with lenalidomide and dexamethasone for patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
- Pembrolizumab (KEYTRUDA) Merck, for patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy.
- Pembrolizumab (KEYTRUDA) Merck, for the first-line treatment of patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC).
- Polatuzumab vedotin-piiq (POLIVY) Genentech, Inc., a CD79b-directed antibody-drug conjugate indicated in combination with bendamustine and a rituximab product for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL).
- Gilteritinib (XOSPATA) Astellas Pharma US, Inc, for adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation.
- Lenalidomide (REVLIMID) Celgene Corp., in combination with a rituximab product for previously treated follicular lymphoma (FL) and previously treated marginal zone lymphoma (MZL).
- Alpelisib (PIQRAY) Novartis Pharmaceuticals Corporation, in combination with fulvestrant for postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.
- Ruxolitinib (JAKAFI) Incyte Corporation, for steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older.
- Dalteparin sodium (FRAGMIN) Pfizer, Inc., to reduce the recurrence of symptomatic venous thromboembolism (VTE) in pediatric patients 1 month of age and older.
- Venetoclax (VENCLEXTA) AbbVie Inc. and Genentech Inc., for adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

- Avelumab (BAVENCIO) EMD Serono, Inc., in combination with axitinib for first-line treatment of patients with advanced renal cell carcinoma (RCC).
- Ramucirumab (CYRAMZA) Eli Lilly and Company, as a single agent for hepatocellular carcinoma (HCC) in patients who have an alpha fetoprotein (AFP) of ≥ 400 ng/mL and have been previously treated with sorafenib.
- Ado-trastuzumab emtansine (KADCYLA) Genentech, Inc., for the adjuvant treatment of patients with HER2-positive early breast cancer (EBC) who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.
- Ivosidenib (TIBSOVO) Agios Pharmaceuticals, Inc., for newly-diagnosed acute myeloid leukemia (AML) with a susceptible IDH1 mutation.
- Pembrolizumab (KEYTRUDA) Merck & Co. Inc., plus axitinib for first-line treatment of patients with advanced renal cell carcinoma (RCC).
- Erdafitinib (BALVERSA) Janssen Pharmaceutical Companies, for locally advanced or metastatic urothelial carcinoma, with susceptible FGFR3 or FGFR2 genetic alterations, that has progressed during or following platinum-containing chemotherapy.
- Pembrolizumab (KEYTRUDA) Merck Inc., for first-line treatment of patients with stage III non-small cell lung cancer (NSCLC) who are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC.
- Atezolizumab (TECENTRIQ) Genentech Inc., in combination with carboplatin and etoposide, for first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
- Atezolizumab (TECENTRIQ) Genentech Inc., for PD-L1 positive unresectable locally advanced or metastatic triple-negative breast cancer.
- Trastuzumab and hyaluronidase-oysk injection (Herceptin Hylecta) Genentech Inc., for the treatment of HER2 overexpressing breast cancer.
- Trifluridine/ tipiracil tablets (LONSURF) Taiho Pharmaceutical Co., Ltd, for adult patients with metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma previously treated with at least two prior lines of chemotherapy.
- Pembrolizumab (KEYTRUDA) Merck, for the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection.
- Caplacizumab-yhdp (CABLIVI) Ablynx NV, for adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.
- Cabozantinib (CABOMETYX) Exelixis, Inc. for hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.
- Darolutamide (NUBEQA) Bayer HealthCare Pharmaceuticals Inc; for non-metastatic castration-resistant prostate cancer.

2018

- Tagraxofusp-erzs (ELZONRIS™) Stemline Therapeutics; a CD123-directed cytotoxin, for blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older. December 21, 2019
- Ravulizumab-cwvz (ULTOMIRIS™) Alexion Pharmaceuticals, Inc.; for adult patients with paroxysmal nocturnal hemoglobinuria (PNH). December 21, 2018
- Calaspargase pegol-mknl (ASPARLAS) Servier Pharmaceuticals LLC; an asparagine specific enzyme, as a component of a multi-agent chemotherapeutic regimen for acute lymphoblastic leukemia (ALL) in pediatric and young adult patients age 1 month to 21 years. December 20, 2018
- Olaparib (LYNPARZA) AstraZeneca Pharmaceuticals LP; for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer. December 19, 2018
- Pembrolizumab (KEYTRUDA) Merck & Co. Inc.; for adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma. December 19, 2018.
- Herzuma (trastuzumab-pkrb) Celltrion Inc.; for patients with HER2-overexpressing breast cancer. December 14, 2018
- Romiplostim (NPLATE) Amgen Inc.; for pediatric patients 1 year of age and older with immune thrombocytopenia (ITP) December 14, 2018

- Atezolizumab (TECENTRIQ) Genentech, Inc.; in combination with bevacizumab, paclitaxel, and carboplatin for the first-line treatment of patients with metastatic non-squamous, non-small cell lung cancer. December 6, 2018
- Gilteritinib (XOSPATA) Astellas Pharma US Inc.; for treatment of adult patients who have relapsed or refractory acute myeloid leukemia. November 28, 2018
- Truxima (rituximab-abbs) Celltrion Inc.; for patients with CD20-positive, B-cell non-Hodgkin's lymphoma. November 28, 2018
- Larotrectinib (VITRAKVIloxo) Oncology Inc. and Bayer; for adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase gene fusion without a known acquired resistance mutation. November 26, 2018
- Venetoclax (VENCLEXTA) AbbVie Inc. and Genentech Inc.; for the treatment of newly-diagnosed acute myeloid leukemia. November 21, 2018
- Glasdegib (DAURISMO) Pfizer Labs; for newly-diagnosed acute myeloid leukemia. November 21, 2018
- Emapalumab (GAMIFANT) Novimmune SA; for adult and pediatric patients with primary hemophagocytic lymphohistiocytosis. November 20, 2018
- Brentuximab vedotin (ADCETRIS) Seattle Genetics Inc.; for previously untreated systemic anaplastic large cell lymphoma or other CD30-expressing peripheral T-cell lymphomas. November 16, 2018
- Pembrolizumab (KEYTRUDA) Merck & Co. Inc.; for patients with hepatocellular carcinoma. November 9, 2018
- Lorlatinib (LORBRENA) Pfizer, Inc.; for patients with anaplastic lymphoma kinase positive metastatic non-small cell lung cancer. November 2, 2018
- Pembrolizumab (KEYTRUDA) Merck & Co. Inc.; as first-line treatment of metastatic squamous non-small cell lung cancer. October 30, 2018
- Talazoparib (TALZENNA) Pfizer Inc.; for locally advanced or metastatic breast cancer. October 16, 2018.
- Emicizumab-kxwh injection (HEMLIBRA) Genentech, Inc. Genentech, Inc.; to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia. October 4, 2018
- Cemiplimab-rwlc (LIBTAYO) Regeneron Pharmaceuticals Inc.; for patients with metastatic cutaneous squamous cell carcinoma or locally advanced CSCC who are not candidates for curative surgery or curative radiation. September 28, 2018.
- VIZIMPRO, Pfizer Pharmaceutical Company for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test. September 27, 2018
- Duvelisib (COPIKTRA, Verastem, Inc.) for adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies. In addition, duvelisib received accelerated approval for adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. September 24, 2018
- Moxetumomab pasudotox-tdfk (LUMOXITI, AstraZeneca Pharmaceuticals LP), a CD22-directed cytotoxin indicated for adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA). September 13, 2018
- Pembrolizumab (KEYTRUDA, Merck & Co., Inc.) in combination with pemetrexed and platinum as first-line treatment of patients with metastatic, non-squamous non-small cell lung cancer (NSqNSCLC), with no EGFR or ALK genomic tumor aberrations. August 20, 2018.
- Keytruda (pembrolizumab) and Tecentriq (atezolizumab) to require the use of an FDA-approved companion diagnostic test to determine PD-L1 levels in tumor tissue from patients with locally advanced or metastatic urothelial cancer who are cisplatin-ineligible. FDA approved two different companion diagnostic tests, one for use with Keytruda and one for use with Tecentriq, August 16, 2018.
- Nivolumab (Opdivo, Bristol-Myers Squibb Company Inc.) for patients with metastatic small cell lung cancer (SCLC) with progression after platinum-based chemotherapy and at least one other line of therapy. August 16, 2018
- Lenvatinib capsules (Lenvima, Eisai Inc.) for first-line treatment of patients with unresectable hepatocellular carcinoma (HCC). August 16, 2018
- Mogamulizumab-kpkc (Poteligeo, Kyowa Kirin, Inc.) for adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy. August 8, 2018

- Lusutrombopag (Mupleta, Shionogi Inc.) for thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a medical or dental procedure. July 31, 2018.
- Iobenguane I 131 (AZEDRA, Progenics Pharmaceuticals, Inc.) for adult and pediatric patients (12 years and older) with iobenguane scan-positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma (PPGL) who require systemic anticancer therapy. July 30, 2018.
- Ivosidenib (Tibsovo, Agios Pharmaceuticals, Inc.) for adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test. July 20, 2018
- Ribociclib (Kisqali, Novartis Pharmaceuticals Corporation) in combination with an aromatase inhibitor for pre/perimenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy. July 18, 2018
- Enzalutamide (XTANDI, Astellas Pharma US, Inc.), for patients with castration-resistant prostate cancer (CRPC). July 13, 2018
- Ipilimumab (YERVOY, Bristol-Myers Squibb Company Inc.) for use in combination with nivolumab for the treatment of patients 12 years of age and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. July 10, 2018
- Tecentriq and Keytruda for patients with locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing therapy. June 19, 2018
- Encorafenib and binimetinib (BRAFTOVI and MEKTOVI, Array BioPharma Inc.) in combination for patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test. June 27, 2018
- Pembrolizumab (Keytruda, Merck) for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy. June 13, 2018
- Bevacizumab (Avastin, Genentech, Inc.) for patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with carboplatin and paclitaxel, followed by single-agent bevacizumab, for stage III or IV disease after initial surgical resection. June 13, 2018
- Pembrolizumab (Keytruda, Merck and Co. Inc.) for patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test. June 12, 2018
- Venetoclax (VENCLEXTA, AbbVie Inc. and Genentech Inc.) for patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy. More Information. June 8, 2018
- Methoxy polyethylene glycol-epoetin beta (Mircera, Vifor Pharma Inc.) for the treatment of pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA. June 7, 2018
- Fulphila (pegfilgrastim-jmdb, Mylan GmbH) as a biosimilar to Neulasta (pegfilgrastim, Amgen, Inc.) to decrease the chance of infection as suggested by febrile neutropenia in patients with non-myeloid cancer who are receiving myelosuppressive chemotherapy that has a clinically significant incidence of febrile neutropenia. June 4, 2018
- Avatrombopag (Doptelet, AkaRx Inc.) for thrombocytopenia in adults with chronic liver disease scheduled to undergo a procedure. May 21, 2018
- Retacrit (epoetin alfa-epbx, Hospira Inc., a subsidiary of Pfizer Inc.) as a biosimilar to Epogen/Procrit (epoetin alfa, Amgen Inc.) for the treatment of anemia due to chronic kidney disease (CKD) in patients on dialysis and not on dialysis, use of zidovudine in patients with HIV infection, and the effects of concomitant myelosuppressive chemotherapy. It is also approved for the reduction of allogeneic red blood cell transfusions in patients undergoing elective, noncardiac, nonvascular surgery. May 15, 2018
- Dabrafenib plus trametinib for anaplastic thyroid cancer with BRAF V600E mutation. May 4, 2018.
- Tisagenlecleucel (KYMRIAHA, Novartis Pharmaceuticals Corp.) a CD19-directed genetically modified autologous T-cell immunotherapy, for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. May 1, 2018.

- Dabrafenib (TAFINLAR, Novartis Pharmaceuticals Corp.) and trametinib (MEKINIST, Novartis Pharmaceuticals Corp.) in combination for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection. April 30, 2018
- Osimertinib (Tagrisso, AstraZeneca Pharmaceuticals LP) for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. April 19, 2018
- Fostamatinib disodium hexahydrate tablets (TAVALISSE, Rigel Pharmaceuticals, Inc.) for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. April 17, 2018
- Nivolumab and ipilimumab (Opdivo and Yervoy, Bristol-Myers Squibb Co.) in combination for the treatment of intermediate or poor risk, previously untreated advanced renal cell carcinoma. April 16, 2018
- Everolimus tablets for oral suspension (Afinitor Disperz, Novartis Pharmaceuticals Corp.) for the adjunctive treatment of adult and pediatric patients aged 2 years and older with tuberous sclerosis complex (TSC)-associated partial-onset seizures. Everolimus is also approved for two other manifestations of TSC: TSC-associated subependymal giant cell astrocytoma (SEGA) and TSC-associated renal angiomyolipoma. April 10, 2018
- Rucaparib for maintenance treatment of recurrent ovarian, fallopian tube, or primary peritoneal cancer. April 6, 2018
- Blinatumomab (Blinicyto, Amgen Inc.) for the treatment of adult and pediatric patients with B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%. March 29, 2018
- Nilotinib (TASIGNA, Novartis Pharmaceuticals Corporation) for pediatric patients 1 year of age or older with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) or Ph+ CML-CP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy. March 22, 2018
- Brentuximab vedotin (Adcetris, Seattle Genetics, Inc.) to treat adult patients with previously untreated stage III or IV classical Hodgkin lymphoma (cHL) in combination with chemotherapy. March 20, 2018
- Abemaciclib (VERZENIO, Eli Lilly and Company) in combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. February 26, 2018
- Durvalumab (Imfinzi, AstraZeneca Inc.) for patients with unresectable stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. February 16, 2018
- Apalutamide for non-metastatic castration-resistant prostate cancer. February 14, 2018
- Abiraterone acetate (Zytiga, Janssen Biotech Inc.) tablets in combination with prednisone for metastatic high-risk castration-sensitive prostate cancer (CSPC). February 7, 2018
- Lutetium Lu 177 dotatate (LUTATHERA, Advanced Accelerator Applications USA, Inc.) a radiolabeled somatostatin analog, for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults. January 26, 2018
- Afatinib (Gilotrif, Boehringer Ingelheim Pharmaceutical, Inc.) for a broadened indication in first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test. January 12, 2018
- Olaparib tablets (Lynparza, AstraZeneca Pharmaceuticals LP), a poly (ADP-ribose) polymerase (PARP) inhibitor, for the treatment of patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), HER2-negative metastatic breast cancer who have been treated with chemotherapy either in the neoadjuvant, adjuvant, or metastatic setting. January 12, 2018

2017

- Pertuzumab – (PERJETA); Genentech, Inc.; for treatment of HER2-positive early breast cancer. Approved December 2017
- Nivolumab – (OPDIVO); Bristol-Myers Squibb; for treatment of melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection. Approved December 2017
- Bosutinib – (BOSULIF); Pfizer Inc.; for treatment of newly-diagnosed chronic phase, Philadelphia chromosome positive, chronic myelogenous leukemia (CML). Approved December 2017

- Cabozantinib – (Cabometyx); Exelixis, Inc.; for treatment of advanced renal cell carcinoma (RCC). Approved December 2017.
- Ogivri – (trastuzumab-dkst); Mylan; for the treatment of HER2-overexpressing breast or metastatic stomach cancer. Approved December 2017
- FoundationOne CDx – (F1CDx); Foundation Medicine, Inc.; in vitro diagnostic to detect genetic mutations in 324 genes and two genomic signatures in any solid tumor type. Approved November 2017
- Sunitinib Malate – (Sutent); Pfizer Inc.; for treatment of recurrent renal cell carcinoma following nephrectomy. Approved November 2017
- Obinutuzumab – (GAZYVA); Genentech, Inc.; for the treatment previously untreated stage II bulky, III, or IV follicular lymphoma. Approved November 2017
- Brentuximab Vedotin – (ADCETRIS); Seattle Genetics, Inc.; for treatment of primary cutaneous anaplastic large cell lymphoma or CD30-expressing mycosis fungoides. Approved November 2017.
- Alectinib – (ALECENSA); Hoffmann-La Roche, Inc./Genentech, Inc.; for treatment of anaplastic lymphoma kinase positive metastatic non-small cell lung cancer. Approved November 2017
- Acalabrutinib – (Calquence); AstraZeneca Pharmaceuticals Inc. under license of Acerta Pharma BV; for treatment of mantle cell lymphoma. Approved October 2017
- Axicabtagene Ciloleucel – (YESCARTA); Kite Pharma, Inc.; for treatment relapsed or refractory large B-cell lymphoma. Approved October 2017
- Abemaciclib – (VERZENIO); Eli Lilly and Company; for treatment of HR-positive, HER2-negative advanced or metastatic breast cancer. Approved September 2017
- Nivolumab – (OPDIVO); Bristol-Myers Squibb Co.; for the treatment of hepatocellular carcinoma. Approved September 2017
- Pembrolizumab – (KEYTRUDA); Merck & Co., Inc.; for treatment of locally advanced or metastatic, gastric or gastroesophageal junction adenocarcinoma. Approved September 2017
- Cabazitaxel – (JEVTANA); Sanofi-Aventis; for treatment metastatic castration-resistant prostate cancer. Approved September 2017
- Copanlisib – (ALIQOPA); Bayer HealthCare Pharmaceuticals Inc.; for treatment of relapsed follicular lymphoma. Approved September 2017
- Mvasi (bevacizumab-awwb); Amgen Inc.; for treatment of cancer. Approved September 2017
- Gemtuzumab Ozogamicin – (Mylotarg); Pfizer Inc.; for treatment of newly-diagnosed CD33-positive acute myeloid leukemia and relapsed or refractory CD33-positive AML. Approved September 2017
- Tisagenlecleucel – (KYMRIAHA); Novartis Pharmaceuticals Corp.; for treatment B-cell precursor acute lymphoblastic leukemia. Approved August 2017
- Olaparib tablets (Lynparza); AstraZeneca; for treatment recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer. Approved August 2017
- Inotuzumab Ozogamicin – (BESPONSA); Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.; for treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia. Approved August 2017
- Liposome-encapsulated combination of Daunorubicin and Cytarabine – (VYXEOS); Jazz Pharmaceuticals, Inc.; for treatment of newly-diagnosed therapy-related AML or AML with myelodysplasia-related changes. Approved August 2017
- Ibrutinib – (Imbruvica); Pharmacyclics LLC; for treatment of chronic graft versus host disease. Approved August 2017
- Enasidenib – (IDHIFA); Celgene Corp.; for treatment of relapsed or refractory acute myeloid leukemia with an isocitrate dehydrogenase-2. Approved August 2017
- Nivolumab – (OPDIVO); Bristol-Myers Squibb Company; for treatment of mismatch repair deficient and microsatellite instability high metastatic colorectal cancer. Approved August 2017
- Neratinib – (NERLYNX); Puma Biotechnology, Inc.; for treatment of early stage HER2-overexpressed/amplified breast cancer. Approved July 2017
- Blinatumomab – (BLINCYTO); Amgen Inc.; for treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia. Approved July 2017

- Praxis Extended RAS Panel – Illumina, Inc.; a next generation sequencing test to detect certain genetic mutations in RAS genes in tumor samples of patients with metastatic colorectal cancer. Approved June 2017
- Betrixaban – (BEVYXXA); Portolafor; the prophylaxis of venous thromboembolism. Approved June 2017
- Dabrafenib and Trametinib – (TAFINLAR and MEKINIST); Novartis Pharmaceuticals Inc.; for treatment of metastatic non-small cell lung cancer with BRAF V600E mutation. Approved June 2017
- Rituximab and Hyaluronidase – (RITUXAN HYCELA); Genentech Inc.; for treatment of follicular lymphoma, diffuse large B-cell lymphoma, and chronic lymphocytic leukemia. Approved June 2017
- Ceritinib – (ZYKADIA); Novartis Pharmaceuticals Corp.; for treatment of metastatic non-small cell lung cancer whose tumors are anaplastic lymphoma kinase positive. Approved May 2017
- Pembrolizumab – (KEYTRUDA); Merck & Co.; for treatment of unresectable or metastatic, microsatellite instability-high or mismatch repair deficient solid tumors. Approved May 2017
- Pembrolizumab – (KEYTRUDA); Merck and Co., Inc.; for treatment of locally advanced or metastatic urothelial carcinoma. Approved May 2017
- Pembrolizumab – (KEYTRUDA); Merck and Co., Inc.; for treatment of metastatic non-squamous non-small cell lung cancer. Approved May 2017
- Avelumab – (BAVENCIO); EMD Serono, Inc.; for treatment of locally advanced or metastatic urothelial carcinoma. Approved May 2017
- Durvalumab – (IMFINZI); AstraZeneca UK Limited; for treatment of locally advanced or metastatic urothelial carcinoma. Approved May 2017
- Brigatinib (ALUNBRIG); Takeda Pharmaceutical Company Limited, through its wholly owned subsidiary ARIAD Pharmaceuticals, Inc.; for treatment of metastatic anaplastic lymphoma kinase positive non-small cell lung cancer. Approved April 2017
- Midostaurin – (RYDAPT); Novartis Pharmaceuticals Corp.; for treatment of newly diagnosed acute myeloid leukemia who are FLT3 mutation-positive. Approved April 2017
- Regorafenib – (STIVARGA); Bayer HealthCare Pharmaceuticals Inc; for treatment of hepatocellular carcinoma. Approved April 2017
- Philips IntelliSite Pathology Solution (PIPS); Philips Medical Systems Nederland B.V.; as an aid to the pathologist to review and interpret digital images of surgical pathology slides prepared from formalin-fixed paraffin embedded. Approved April 2017
- Ipsogen JAK2 RGQ PCR Kit – QIAGEN GmbH.; to detect mutations affecting the Janus Tyrosine Kinase 2 gene. Approved March 2017
- Palbociclib – (IBRANCE); Pfizer Inc.; for treatment of hormone receptor positive human epidermal growth factor receptor 2 negative advanced or metastatic breast cancer. Approved March 2017
- Osimertinib – (TAGRISSO); AstraZeneca Pharmaceuticals, LP; for treatment of metastatic epidermal growth factor receptor T790M mutation-positive non-small cell lung cancer. Approved March 2017
- Niraparib – (ZEJULA); Tesaro, Inc.; for treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer. Approved March 2017
- Avelumab – (BAVENCIO); EMD Serono, Inc.; for treatment of metastatic Merkel cell carcinoma. Approved March 2017
- Pembrolizumab – (KEYTRUDA); Merck and Co., Inc.; for treatment of refractory classical Hodgkin lymphoma or those who have relapsed after three or more prior lines of therapy. Approved March 2017
- Ribociclib – (KISQALI); Novartis Pharmaceuticals Corp.; for treatment of postmenopausal hormone receptor positive human epidermal growth factor receptor 2 negative advanced or metastatic breast cancer. Approved March 2017
- Lenalidomide – (Revlimid); Celgene Corp.; for treatment of multiple myeloma following autologous stem cell transplant. Approved February 2017
- Nivolumab – (OPDIVO); Bristol-Myers Squibb Company; for treatment of locally advanced or metastatic urothelial carcinoma. Approved February 2017

2016

- Rubraca – (rucaparib); Clovis Oncology; For the treatment of women with a certain type of ovarian cancer
- Lartruvo – (olaratumab); Eli Lilly; For the treatment of adults with certain types of soft tissue sarcoma
- Tecentriq – (atezolizumab); Genentech; For the treatment of urothelial carcinoma, the most common type of bladder cancer
- Venclexta – (venetoclax); Abbvie and Genentech; For the treatment of chronic lymphocytic leukemia in patients with a specific chromosomal abnormality

2015

- Cotellic – (cobimetinib); Genentech; For the treatment of BRAF V600E or V600K melanoma, Approved November 2015
- Darzalex- (daratumumab); Janssen Biotech; For the treatment of multiple myeloma, Approved November 2015
- Imlygic – (talimogene laherparepvec); Amgen; For the treatment of unresectable recurrent melanoma, Approved October 2015
- Lonsurf – (trifluridine and tipiracil); Taiho Oncology; For the treatment of metastatic colorectal cancer , Approved September 2015
- Opdivo – (nivolumab); Bristol-Myers Squibb; For the treatment of metastatic squamous non-small cell lung cancer, Approved March 2015

2014

- Azynzeo – (netupitant and palonosetron); Helsinn; For the prevention of chemotherapy-induced nausea and vomiting, Approved October 2014
- Imbruvica – (ibrutinib); Pharmacyclics; For the treatment of chronic lymphocytic leukemia, Approved February 2014
- Lynparza – (olaparib); AstraZeneca; For the treatment of previously treated BRCA mutated advanced ovarian cancer, Approved December 2014
- Opdivo – (nivolumab); Bristol-Myers Squibb; For the treatment of unresectable or metastatic melanoma, Approved December 2014
- Zydelig – (idelalisib); Gilead; For the treatment of relapsed CLL, follicular B-cell NHL and small lymphocytic lymphoma, Approved July 2014

2013

- Gilotrif – (afatinib); Boehringer Ingelheim; For the treatment of metastatic non-small cell lung cancer with EGFR mutations
- Imbruvica – (ibrutinib); Pharmacyclics; For the treatment of mantle cell lymphoma, Approved November of 2013
- Pomalyst – (pomalidomide); Celgene; For the treatment of relapsed and refractory multiple myeloma
- Stivarga – (regorafenib); Bayer; For the treatment of gastrointestinal stromal tumor

2012

- Subsys – (fentanyl sublingual spray); Insys Therapeutics; For the treatment of breakthrough cancer pain
- Pertuzumab – (perjeta); Roche; For the treatment of HER2-positive metastatic breast cancer
- Carfilzomib – (kyprolis); Onyx Pharmaceuticals; For the treatment of multiple myeloma
- Ziv-aflibercept – (zaltap); Sanofi; For the treatment of metastatic colorectal cancer

2011

- Lazanda – (fentanyl citrate) nasal spray; Archimedes; For the management of breakthrough cancer pain
- Zytiga – (abiraterone acetate); Centocor Ortho Biotech; For the treatment of prostate cancer

2010

- Halaven – (eribulin mesylate); Eisai; For the treatment of metastatic breast cancer
- Jevtana – (cabazitaxel) ; Sanofi Aventis; For the treatment of prostate cancer

2009

- Onsolis – (fentanyl buccal); BioDelivery Sciences; For the management of breakthrough cancer pain
- Afinitor – (everolimus); Novartis; For the treatment of renal cell carcinoma
- Folutyn– (pralatrexate injection); Allos Therapeutics; For the treatment of peripheral T-cell lymphoma

2008

- Sancuso – (granisetron); ProStrakan; For the treatment of chemotherapy-induced nausea and vomiting

2006

- Sutent– (sunitinib); Pfizer; For the treatment of kidney cancer and gastrointestinal stromal tumors

2005

- Nexavar – (sorafenib); Bayer/Onyx; For the treatment of Renal Cell Carcinoma